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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/076,727

02/13/2002

John T. Groves

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7590

07/24/2008

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/076,727

**Applicant(s)**

GROVES ET AL.

**Examiner**

Mark L. Shibuya, Ph.D.

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-20 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) 13, 19, 25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-12, 14-18, 20 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

1. Application 10076727, (20020160505 A1): Claims 7-20 and 25-27 are pending. Claims 13, 19, 25 and 27 are withdrawn from consideration. Claims 7-12, 14-18, 20 and 26 are examined.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/2008 has been entered.

#### ***Election/Restrictions***

3. Applicant's election of the species of major histocompatibility complex as a final species of dopant molecules in the reply filed on 2/23/2007 is once again acknowledged, (see Office action mailed 4/27/2007). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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4. Claims 13, 19, 25 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/23/2007.

***Priority***

5. This application, 10/076,727, filed 2/13/2002, claims benefit of 60/269,625, filed 2/16/2001, and claims benefit of 60/296,952, filed 6/8/2001.

***Withdrawn Claim Objections/Rejections***

6. The applicant's Reply, entered 5/5/2008, has been considered. Rejections and/or objections not reiterated from the previous Office action, mailed 11/5/2008, are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

7. The following claim rejections/objections are withdrawn in view of applicant's arguments and amendments to the claims:

8. Claims 7-20, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. Claims 14-20, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 7, 8, 10, 11, and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dori et al., Biomedical Materials Research, (Sept. 7, 1999), p. 75-81, (IDS entered 5/26/2005).

***Claim Rejections - 35 USC § 112, Second Paragraph***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 7 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 states the language "is different from at least one an adjacent corral", which renders the claim vague and indefinite because it is unclear as to what "one" is.

The term "sufficiently small" in claim 15 is a relative term which renders the claim indefinite. The term "sufficiently small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of "smallness", and

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one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 7-12, 14-18, 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Boxer**, Current Opinions in Chemical Biology, Dec. 2000, Vol. 4, pp. 704-709, and in view of **Cremer** et al., J. Am. Chem. Soc., Aug. 1999, Vol. 121, pp. 8130-8131, (IDS filed 5/15/02); and **Grakoui** et al., Science, Jul. 1999, Vol. 285, pp. 221-227, (IDS filed 5/15/02).

The claims are drawn to a method for screening living cell adhesion on a solid substrate comprising: a) contacting a living cell with a micro-array comprising a substrate comprising an array of adjacent membrane corrals, wherein the corrals contain lipid bilayer membranes above an aqueous layer, wherein said lipid bilayer membranes in each of said corrals are doped with one or more dopants to form a doped lipid bilayer membrane, said dopants selected from the group consisting of charged lipids and membrane proteins, and wherein the dopants selected in each corral is different from at least an adjacent corral; and b) allowing said living cell to sample one or more of the doped lipid bilayer membranes; and c) observing cell interaction and adhesion to the doped lipid bilayer membranes in a specific corral after a time period of at least one hour, whereby the dopants direct cell interaction and adhesion; and variations thereof.

**Boxer**, Current Opinions in Chemical Biology, Dec. 2000, Vol. 4, pp. 704-709, throughout the publication, and the abstract, and at p. 706, teaches contacting living cells with supported lipid bilayer membranes, wherein the lipid bilayer membranes comprise cell recognition components, and including supported membranes decorated with receptor protein, reading on a dopant that is a membrane protein. **Boxer**, at p. 708,

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states that functional membranes proteins. Boxer, at p. 704, para 3, teach that the lipid bilayer of supported membranes is separated from the solid support by a thin layer of water.

Boxer does not appear to explicitly disclose arrays of adjacent membrane corrals. Boxer does not appear to explicitly teach different membrane proteins which are selected dopants that are different the dopants from at least one other corral.

**Cremer** et al., J. Am. Chem. Soc. 1999, Vol. 121, pp. 8130-8131, throughout the publication, and at p. 8130, teach that the use of planar supports for presenting large arrays of spatially addressed molecules is one of the most powerful and versatile methods for creating combinatorial libraries for use in rapid screening assays. Cremer et al. at p. 8130, teach expanding this approach to supported phospholipid bilayer membranes containing peptides, receptors and integral membrane proteins, in order to mimic cell surface properties. Cremer et al., at p. 8130, para 3, Fig. 2, teach a 3 X 3 array of glass well plates, reading on the "corrals" of the instant claims, which contain addressed egg phosphatidylcholine lipid membranes with various dyes. Cremer et al., at p. 8131, Fig. 3, teach selective incorporation of a protein receptor site into patterned membranes. Thus Cremer et al. explicitly disclose arrays of adjacent membrane corrals.

**Grakoui** et al., Science, Jul. 1999, Vol. 285, pp. 221-227, throughout the publication and abstract, and at p. 221, para 1, p. 226, note 14, teach T cell activation mediated by adhesion molecules, wherein T cell antigen receptors interact with ligands, major histocompatibility molecules-peptide complexes. Grakoui et al., at pp. 221, para

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7, teach a T cell activating system wherein the antigen presenting cell is replaced with planar bilayers containing fluorescently labeled MHC-peptide and ICAM-1.

Furthermore, Grakoui et al., at p. 226, Fig. 6, teach LFA as a membrane protein involved in cell adhesion. Thus Grakoui et al. teach supported membranes displaying different specific proteins, which include MHC and ICAM, that are effective artificial cell surfaces for adhesion with living cells.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to have made and used a method for screening living cell adhesion comprising an array of adjacent membrane corrals, wherein the corrals contain lipid bilayer membranes above an aqueous layer, wherein said lipid bilayer membranes in each of said corrals are doped with one or more dopants to form a doped lipid bilayer membrane, said dopants being membrane proteins.

One of ordinary skill in the art would have been motivated to make and use methods comprising arrays of adjacent membrane corrals and wherein the membrane protein dopants which are selected are different the dopants from at least one other corral because Cremer et al. teaches the use of arrays of corralled lipid bilayers in screening assays and because Grakoui et al. teach the use of supported membranes displaying different membrane protein as effective artificial surfaces.

### ***Conclusion***

15. Claims 7-12, 14-18, 20 and 26 are rejected.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D. whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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